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NCIC HPV
Sent by: Mary-Beth Weaver

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To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on Nitroalcohols

Richard_Denison@environmentaldefense.org on 07/10/2003 06:35:32 PM

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Subject: Environmental Defense comments on Nitroalcohols

(Submitted via Internet 7/10/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and AFBollmeier@dow.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Nitroalcohols.

This test plan and set of robust summaries was prepared by Dow Chemical. It is a category submission covering two nitroalcohols: 2-(hydroxymethyl) -2-nitro-1,3 propanediol (TN, CAS #126-11-4) and 2-methyl-2-nitro-1-propanol (MNP, CAS# 76-39-1). According to the sponsor, the major uses of the nitroalcohols are as closed-system intermediates in the production of alkanolamines. However, TN is also used as a biocide and as a cross-linker in plywood and as a biocide in other applications. Due to its use as a biocide, it is registered under FIFRA and therefore has a relatively complete screening-level dataset. Very little information is available on MNP, and the sponsor proposes to use data from TN to satisfy requirements for the HPV program.

Overall, this is a well-written submission and it contains much useful information. However, we do have some concerns that should be addressed in a revised submission. In particular, the justification for a category designation is inadequate, although it is likely that we would support the category proposal if appropriate information is added to the test plan. We also recommend the sponsor conduct plant toxicity and developmental studies for MNP. Specific comments are as follows:

1. The only justification for provided for the category is that the two nitroalcohols have similar LD50's and they appear to be structurally similar. This is not an adequate level of information to justify a category. The sponsor should organize the data for the chemicals in a meaningful way to provide a convincing justification. For example, comparable properties from other endpoints should be organized into a tabular form with supporting narrative. Differences should also be addressed: Why, for example, is MNP a potent eye irritant and TN is not? This difference indicates that the two chemicals do not act in fact alike in biological systems. (We would note that these nitroalcohols would be good candidates to apply gene expression technologies in in vitro systems to determine with more surety if they do belong together in a category.)

2. TN has low toxicity to aquatic invertebrates and fish but it does possess significant toxicity to algae. Therefore, we recommend that a plant toxicity study be conducted on MNP to determine if it is also toxic to plants.

3. The sponsor states that MNP, unlike TN, is exclusively used as a closed-system intermediate. EPA's guidance on closed-system intermediates (see www.epa.gov/chemrtk/closed9.htm) specifies what information needs to be provided to warrant granting of closed-system intermediate status to a chemical. These data have not been provided for MNP, without which such status cannot be assumed and the associated reduced testing requirements do not apply.

Given the superficial justification for category formation, we believe a developmental toxicity study needs to be conducted on MNP. In addition, until and unless the burden of demonstrating closed-system intermediate status for MNP has been met, repeated dose and reproductive toxicity studies are also required.

4. Genetic toxicity studies are sufficient to conclude that neither TN nor MNP possesses genotoxic activity.

5. TN does appear to exhibit neurotoxic properties based on effects on purkinje cells in ducklings. The test plan needs to address whether MNP would be expected to cause the same effect and if so what the comparative potencies of MNP and TN would be.

Thank you for this opportunity to comment.

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